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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,945	03/07/2007	Philip A. Beachy	JHU1920-1	2047
28213	7590	01/28/2011		
DLA PIPER LLP (US) 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133			EXAMINER REESE, HEIDIL	
			ART UNIT	PAPER NUMBER
			1625	
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			01/28/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/573,945

Applicant(s)

BEACHY ET AL.

Examiner

Heidi Reese

Art Unit

1625

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 24, 25 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 5 is/are allowed.
- 6) ☒ Claim(s) 1, 24, 25 and 42-44 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 3, 2010, has been entered.

Response to Amendment

2. Applicant's amendment and Rule 132 affidavit filed on May 3, 2010, are acknowledged. Claims 1-5, 24, 25, and 42-44 are pending in this application and are under examination. Claims 6-23, 26-41, and 45-59 were previously withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections Withdrawn

3. The rejection of claims 1-5, 24, 25, and 42-44 are under the first paragraph of 35 U.S.C. §112, as lacking enablement commensurate with the scope of the claims, is withdrawn in response to Applicant's amendment, affidavit, and arguments.

Claim Rejections Maintained

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The rejection of claims 24 and 42-44 under 35 U.S.C. §103(a) is maintained for reasons of record in the office actions dated March 30, 2009, and January 5, 2010. Applicant's arguments have been fully considered but have not been found to be persuasive. Applicants again dispute the Office's establishment of a prima facie case of obviousness, arguing that the combined Patani and Hcaplus 1999:486717 references lack the motivation to substitute a pyridine ring for a phenyl ring in the Hcaplus 1999:486717 compounds to arrive at the claimed compounds.

6. However, the required motivation is inherent in the general discussion in Patani of bioisosterism and its application in drug discovery. Applicants are referred to MPEP 2144 Section IV, wherein it is explained that the motivation to modify a reference need not arise in connection with the result discovered by an applicant. Based on the general principle of bioisosterism and the documented bioisosterism of phenyl and pyridyl, the artisan would expect the corresponding 4-ethyl pyridyl compounds to work at least as well as the 4-ethyl phenyl compounds disclosed by the Hcaplus reference for the purpose disclosed by that reference. Under MPEP 2144 Section IV, such expectation is sufficient to satisfy the requirement for motivation to modify. Therefore, it is concluded that prima facie obviousness is established and that the burden of going forward now shifts to applicant to submit evidence of non-obviousness.

7.

New Grounds of Objection and Rejection

Claim Objections

8. Claims 2 and 3 are objected to as depending from a rejected base claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim 24 and 25 are newly rejected under 35 U.S.C. §102(e) as anticipated by WO2004/056774 to Bakthavatchalam et al. At pages 105-110 Bakthavatchalam '774 discloses N-substituted alkylpyridylbenzamides -- compounds 407, 412, 414, 420, and 455 -- which are within the genus of claim 24 and the subgenus of claim 25.

Claim Rejections - 35 USC § 103

11. Claim 1 is newly rejected under 35 U.S.C. §103(a), as obvious over the combined Patani and Hcaplus 1999:486717 references which are already of record. The basis for this rejection -- bioisosteric substitution of pyridyl for phenyl -- is identical to that of the previous rejections made over this combination of references. Save for the substitution of pyridyl for phenyl, the four compounds of Hcaplus 1999:486717 which were cited in the previous Office Actions would anticipate the genus of formula I.

12. Claims 1 and 42-44 are also newly rejected under 35 U.S.C. §103(a), as obvious over WO2004/056774 to Bakthavatchalam et al. Bakthavatchalam '774 teaches N-(4-tert-butyl-phenyl)-4-(3-dimethylaminomethyl-pyridin-2-yl)-benzamide (compound 407, page 105) and N-(4-tert-butyl-phenyl)-4-(3-methyl-pyridin-2-yl)-benzamide (compound 414, page 106), both of which are position isomers of the generic structure of claim 1.

Allowable Subject Matter

13. Claims 4 and 5 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heidi Reese, whose telephone number is (571) 270-5277. The examiner can normally be reached on Monday-Thursday 8 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Andres/
Supervisory Patent Examiner, Art Unit 1625

/Heidi Reese/
Examiner, Art Unit 1625